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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/783,253	02/13/2001	Motasim Sirhan	020460000910	1700

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EXAMINER
PHAN, HIEU

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 09/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/783,253	SIRHAN ET AL.	
	Examiner	Art Unit	
	Hieu Phan	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-101* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-101* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-63 and 94-101, drawn to a luminal prosthesis, classified in class 623, subclass 1.42.

II. Claims 64-93, drawn to method of delivering a luminal prosthesis, classified in class 128, subclass 898.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product such as implanting a luminal prosthesis that does not contain medical substances, for example, collagen and anti-platelet agents..

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Upon election of Group I, a further election of specie is required. The application contains claims directed to the following patentably distinct species of the claimed invention:

A) Specie 1: Figure 1

B) Specie 2: Figures 1A and 4

C) Specie 3: Figure 5

D) Specie 4: Figure 6

E) Specie 5: Figure 7

F) Specie 6: Figure 8

G) Specie 7: Figure 9

H) Specie 8: Figure 10.

5. Upon election of Group I and one of the Specie in paragraph 4, a further election of Sub-Specie I is required. The application contains claims directed to the following patentably distinct species of the claimed invention:

A) Specie 1: initial phase of substance delivery is less than 12 weeks

B) Specie 2: initial phase of substance delivery is within a time period of 1 hours to 8 weeks

C) Specie 3: initial phase of substance delivery is within a time period of 12 hours to 2 weeks

D) Specie 4: initial phase of substance delivery is within a time period of 1 day to 1 week.

6. Upon election of Group I and one of the Specie in paragraph 4, a further election of Sub-specie II is required. The application contains claims directed to the following patentably distinct species of the claimed invention:

A) Specie 1: Subsequent phase of substance delivery is within a time period of 4 hours to 24 weeks

B) Specie 2: Subsequent phase of substance delivery is within a time period of 1 day 1 to 12 weeks

C) Specie 3: Subsequent phase of substance delivery is within a time period of 2 days to 8 weeks

D) Specie 4: Subsequent phase of substance delivery is within a time period of 3 days to 50 days.

7. Upon election of Group I and one of the Specie in paragraph 4, a further election of Sub-Specie III is required. The application contains claims directed to the following patentably distinct species of the claimed invention:

A) Specie 1: the substance delivery rate at the initial phase is between 0 micro-grams/day to 30 micrograms/day

B) Specie 2: the substance delivery rate at the initial phase is between 5 micro-grams/day to 30 micrograms/day

8. Upon election of Group I and one of the Specie in paragraph 4, a further election of Sub-Specie IV is required. The application contains claims directed to the following patentably distinct species of the claimed invention:

A) Specie 1: the substance delivery rate at the subsequent phase is between 5 micro-grams/day to 200 micrograms/day

B) Specie 2: the substance delivery rate at the subsequent phase is between 10 micro-grams/day to 100 micrograms/day

9. Upon election of Group I and one of the Specie in paragraph 4, a further election of Sub-Specie V is required. The application contains claims directed to the following patentably distinct species of the claimed invention:

A) Specie 1: mammalian tissue concentration of the substance at the initial phase is within a range from 0 microgram/milligram of tissue to 100 microgram/milligram of tissue

B) Specie 2: mammalian tissue concentration of the substance at the initial phase is within a range from 0 microgram/milligram of tissue to 10 microgram /milligram of tissue.

10. Upon election of Group I and one of the Specie in paragraph 4, a further election of Sub-Specie VI is required. The application contains claims directed to the following patentably distinct species of the claimed invention:

A) Specie 1: mammalian tissue concentration of the substance at the subsequent phase is within a range from 1 picrogram/milligram of tissue to 100 micrograms/milligram of tissue

B) Specie 2: mammalian tissue concentration of the substance at the subsequent

phase is within a range from 1 nanoogram/milligram of tissue to 10 microgram/milligram of tissue

11. Upon election of Group II, a further election of specie is required. The application contains claims directed to the following patentably distinct species of the claimed invention:

A) Specie 1: method for implanting a prosthesis that is programmed to begin substantial release of the pharmacological agent beginning after growth of at least one layer of cells over a part of the prosthesis

B) Specie 2: method for implanting a prosthesis in a body lumen so that a portion of the matrix degrades over a predetermined time period ands substantial substance release begins after the matrix substantially begins to degrade.

C) Specie 3: method for implanting a luminal prosthesis with a rate limiting barrier and the barrier release the substantial substance after preselected time period.

D) Specie 4: method for implanting a luminal prosthesis with a nondegradable matrix and the matrix release the substantial substance after preselected time period

E) Specie 5: method for implanting a luminal prosthesis, wherein the prosthesis incorporates a substance into lumen or lumen wall; and the substance is released by directing energy at the prosthesis

F) Specie 6: method for implanting a luminal prosthesis, wherein the prosthesis incorporates magnetic particles coupled to a matrix formed over the prosthesis; and the particles are released by directing a magnetic field at the prosthesis

G) Specie 7: method for implanting a luminal prosthesis, wherein the prosthesis incorporates magnetic particles coupled to a rate-limiting barrier formed over the prosthesis; and the particles are released by directing a magnetic field at the prosthesis.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hieu Phan whose telephone number is 703-308-8969. The examiner can normally be reached on Monday-Friday from 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0873.

Hieu Phan
Examiner
Art Unit 3738

September 19, 2002

Paul B. Prebilic
Primary Examiner